

CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

**APPLICATION NUMBER
21-064**

Microbiology Review(s)

AUG 27 1999

REVIEW FOR HFD-160
OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF
MICROBIOLOGIST'S REVIEW #2 OF NDA

August 25, 1999

- A. 1. NDA 21-064 Amendment BI

SPONSOR Dupont Pharmaceuticals Company
331 Treble Cove Road
North Billerica, MA 01862

2. PRODUCT NAMES: DEFINITY™ (Perflutren)
3. DOSAGE FORM AND ROUTE OF ADMINISTRATION: Injectable Suspension, IV
4. METHOD(S) OF STERILIZATION:
5. PHARMACOLOGICAL CATEGORY: Ultrasound Contrast Agent
6. DRUG PRIORITY CLASSIFICATION:

- B. 1. DATE OF INITIAL SUBMISSION: December 9, 1998
2. DATE OF AMENDMENT: July 19, 1999
3. RELATED DOCUMENTS: Microbiologist's review #1 of NDA (April 5, 1999)
4. ASSIGNED FOR REVIEW: July 21, 1999

- C. REMARKS: This review covers the sponsors answers to microbiology deficiencies in the original NDA.

D. CONCLUSIONS: This submission is recommended for approval on the basis of sterility assurance.

/S/

8-25-99

Bryan Riley, Ph.D.

cc:

HFD 160/Consult File
HFD 160/K. Cho
HFD 160/R. Kasliwal
HFD 805/Consult File
HFD 805/B. Riley

Drafted by: B. Riley, 8/25/99
R/D initialed by: P. Cooney,

/S/

For PHC

8-27-99

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APR 8 1999

REVIEW FOR HFD-160
OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF
MICROBIOLOGIST'S REVIEW #1 OF NDA

April 5, 1999

A. 1. NDA 21-064

SPONSOR Dupont Pharmaceuticals Company
331 Treble Cove Road
North Billerica, MA 01862

2. PRODUCT NAMES: DEFINITY™ (Perflutren)

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION: Injectable Suspension, IV

4. METHOD(S) OF STERILIZATION:

5. PHARMACOLOGICAL CATEGORY: Ultrasound Contrast Agent

6. DRUG PRIORITY CLASSIFICATION:

B. 1. DATE OF INITIAL SUBMISSION: December 9, 1998

2. DATE OF AMENDMENT: N/A

3. RELATED DOCUMENTS: None

4. ASSIGNED FOR REVIEW: December 11, 1998

C. REMARKS: Definity™ consists of: Perfluoropropane gas, a mixture of three lipids, saline, propylene glycol, and glycerin. The drug product is and then

- D. CONCLUSIONS: This application is approvable on the basis of sterility assurance, pending resolution of certain microbiology issues. Please see "Microbiologist's List of Deficiencies".

/S/
Bryan Riley, Ph.D.

4-5-99

TR 2/8/99

cc:

HFD 160/Consult File
HFD 160/K. Cho
HFD 160/R. Kasliwal
HFD 805/Consult File
HFD 805/B. Riley

Drafted by: B. Riley, 4/5/99
R/D initialed by: P. Cooney,